PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office, PCT
2011 South Clark Place Room CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 24 April 2001 (24.04.01)	
International application No. PCT/US00/20574	**Applicant's or agent's file reference** B0410/7284WO
International filing date (day/month/year) 28 July 2000 (28.07.00)	**Priority date** (day/month/year) 30 July 1999 (30.07.99)
Applicant GAMBALE, Richard, A.	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

27 February 2001 (27.02.01)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Maria Kirchner
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

10/024205
2000

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference B0410/7284WO	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US00/20574	International filing date *(day/month/year)* 28 JULY 2000	Priority date *(day/month/year)* 30 JULY 1999
International Patent Classification (IPC) or national classification and IPC IPC(7): A61F 2/06; A61M 25/00 and US Cl.: 623/1.15, 1.22, 1.36, 901		
Applicant C.R. BARD, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 10 sheets.

3. This report contains indications relating to the following items:

   - I [X] Basis of the report
   - II [ ] Priority
   - III [X] Non-establishment of report with regard to novelty, inventive step or industrial applicability
   - IV [ ] Lack of unity of invention
   - V [X] Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI [ ] Certain documents cited
   - VII [ ] Certain defects in the international application
   - VIII [ ] Certain observations on the international application

Date of submission of the demand	Date of completion of this report
27 FEBRUARY 2001	28 JANUARY 2002
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer BRUCE E. SNOW Telephone No. (703) 308-0858

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US00/20574

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed

☒ the description:
pages (See Attached), as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:
pages (See Attached), as originally filed
pages _____, as amended (together with any statement) under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the drawings:
pages (See Attached), as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the sequence listing part of the description:
pages (See Attached), as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages NONE

☒ the claims, Nos. 15

☒ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

***Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US00/20574

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. 16-18

because:

☐ the said international application, or the said claim Nos. _ relate to the following subject matter which does not require international preliminary examination *(specify)*.

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _ are so unclear that no meaningful opinion could be formed *(specify)*.

☒ the claims, or said claims Nos. 16-18 are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US00/20574

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	12-14	YES
	Claims	1-11, 19-24	NO
Inventive Step (IS)	Claims	none	YES
	Claims	1-14, 19-24	NO
Industrial Applicability (IA)	Claims	1-14, 19-24	YES
	Claims	none	NO

2. citations and explanations (Rule 70.7)

Claims 1-11, 19-24 lack novelty under PCT Article 33(2) as being anticipated by EP 0876 803 (C.R. Bard, Inc.). EP ('803) teaches a tissue implant, a coiled stent formed from stainless steel ribbon material, which is configured to resist migration out of the tissue by having tissue engaging protrusions on its outside surface (col. 6, lines 46-55; col. 7, lines 38-52; col. 8, line 55 - col. 9, line 42; col 10, lines 38-55).
Regarding claim 1, see barbs 73.

Claims 12-14 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of Chuter (5,833,699). Chuter ('699) teaches forming an improved stent using a coiled ribbon produced from a single sheet of metal by etching,which stent is capable of differential elongation. Using the coiled ribbon formed according to the method taught by Chuter in the implant of the type taught by EP '803 would not constitute an inventive step.

NEW CITATIONS

NONE

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

I. BASIS OF REPORT:

This report has been drawn on the basis of the description,
page(s) 1-3, 8, 9, as originally filed.
page(s) NONE, filed with the demand.
and additional amendments:
Pages 4-7, filed with the letter of 22 October 2001

This report has been drawn on the basis of the claims,
page(s) NONE, as originally filed.
page(s) NONE, as amended under Article 19.
page(s) NONE, filed with the demand.
and additional amendments:
Pages 10-12, filed with the letter of 22 October 2001.

This report has been drawn on the basis of the drawings,
page(s) 1-3, as originally filed.
page(s) NONE, filed with the demand.
and additional amendments:
1-3, filed with the letter of 18 September 2000

This report has been drawn on the basis of the sequence listing part of the description:
page(s) NONE, as originally filed.
pages(s) NONE, filed with the demand.
and additional amendments:
NONE

perpendicular orientation discussed above and may enhance anchoring capability by presenting a leading proximal facing edge that serves to grip into tissue.

Barbs formed on the proximally facing edge of the finished implant may be formed on the ribbon prior to winding into its coiled shape. Preferably, the ribbon is formed having barbed shapes along at least one edge of the ribbon by an etching process. A number of ribbons may be etched on a sheet of suitable material, such as stainless steel, at once. After the ribbons are formed on the sheet of material, they may be individually detached from the sheet and wound on a spring winding machine to form a coil by conventional spring winding techniques.

A variety of filament materials may be used such as surgical grade stainless steels. Other materials may be used to vary the modulus of elasticity of the filament. Additionally, flexibility of the coil implant may be varied along the length of the coil, not only by varying spacing between coils and diameter of the filament along its length, but also by using two or more different filament materials along the length of the filament that have different moduli of elasticity.

It is an object of the present invention to provide a tissue implant device that resists migration from the tissue into which it is implanted by offering improved anchoring capability.

It is another object of the present invention to provide a tissue implant device having an anchor mechanism that is easy to integrate into small mechanical devices.

It is yet another object of the present invention to provide an implant device that resists migration by its inherent flexibility and ability to absorb migratory forces exerted by surrounding tissue.

It is another object of the invention to provide an implant device that utilizes an anchoring mechanism that is submerged beneath the surface of the tissue into which the device is implanted.

It is yet another object of the invention to provide a method of implanting a tissue implant device so that it remains anchored in the tissue.

Brief Description of the Drawings

The foregoing and other objects and advantages of the invention will be appreciated more fully from the following further description thereof, with reference to the accompanying diagrammatic drawings wherein:

FIG. 1 is a side view of an alternate embodiment of the tissue implant device;

FIG. 2 is a partial sectional view of the tissue implant device shown in FIG. 13;

FIG. 3 is a partial sectional view of a variation of the tissue implant device shown in FIG. 2;

FIG. 4 is a side view of a preferred embodiment of the tissue implant device having barbs;

FIG. 5 is a side view of an alternate embodiment of the tissue implant device having barbs;

FIG. 6 is a top view of a sheet of material having a plurality of etched ribbon forms through out its surface.

FIG. 7 is a magnified view of one of the etched ribbon forms on the sheet shown in FIG. 6:

FIG. 8A. is a side view of a tissue implant device delivery system;

FIG. 8B is a detailed side view of the distal end of the tissue implant device delivery system; and

FIG. 8C is a detailed side view of the distal end of the tissue implant device delivery system carrying an implant.

Description of the Illustrative Embodiments

The implant devices of the present invention are particularly useful in treating ischemic tissue such as that, which occurs in a myocardium of the heart. The implant device may be inserted into the myocardium through the epicardial surface at an entry site such that the device extends the majority of the thickness of the myocardium towards endocardial surface.

FIG. 1 shows an embodiment of a tubular implant device. The canted coil device 40 is formed from a filament 42 of rectangular cross-section such as a strand of flat wire. As shown in FIG. 2, the coil is formed so that the major cross-sectional

axis 47 of the rectangular wire is oriented at an acute angle to the longitudinal axis 50 of the coil 40. The orientation gives each turn 46 of the coil a projecting edge 44, which tends to claw into tissue to serve as an anchoring mechanism for the device.

FIG. 3 shows a segment of a wrapped ribbon implant embodiment. The implant 60 is formed by a rectangular cross-sectional filament wrapped around a ribbed mandrel. In the present embodiment, the major axes 47 of the rectangular cross-section ribbon is oriented substantially perpendicular to the longitudinal axis 50 of the implant, as is shown in FIG. 3. In this configuration, the major axis 47 of the coils 42 of the rectangular ribbon do not extend radially from the longitudinal axis 50 of the implant 40 at an acute angle. With greater coil surface area extending away from the longitudinal axis of the implant, the implant is believed to be more stable and less likely to migrate once implanted within the myocardium. The implant is preferably formed from 316 stainless steel rectangular cross-section forming wire. Preferred dimensions for the rectangular cross-section filament are on the order of .003 inches to .005 inches for the minor axis width and .015 to .018 inches for the major axis.

FIG. 4 shows a preferred embodiment of the wrapped ribbon device 62 having a plurality of barbs 64 formed on the proximally facing edge 66 of the ribbon. The device may only have one barb, but a plurality of barbs is preferred. Each barb has a tapering penetrating shape configured to claw into tissue to resist migration of the device. The barbs may be a variety of shapes such as the curved shape shown in the figures or a sharp pointed shape (not shown). Barbs 64 formed on the spring embodiment shown in Figure 1 tend to project radially outward from the longitudinal axis of the device at an acute angle, as shown in Figure 4. The radial projection of the barbs may help to anchor the implant within tissue.

Alternatively, as shown in Figure 5, the spring device 68 may have coil 70 oriented such that the major axis is parallel to the longitudinal axis of the device and barbs 64 are curved radially outward from the proximally facing edge 72 of each coil 70. The barbs may be curved by bending prior to wrapping of the ribbon into a coil form.

Ribbon material having integrally formed barbs may be formed by variety of methods; however, chemically etching of the ribbon having barbed shapes is

preferred. FIG. 6 shows a top view of a sheet 76 of material having a plurality of ribbon forms 78 that have been etched through its surface. FIG. 7 shows a magnified view of a single ribbon form 78 comprising a linear ribbon form 79 of a plurality of barb 64, which will ultimately be wrapped into the spring device. Each form 78 remains joined to the sheet 76 after etching by links 77. Ribbon forms are preferably created by a photo etching process. In this process, a photo resistant coating is first applied over the entire sheet of material. Preferably a sheet of stainless steel material is used to having a thickness equivalent to the desired thickness of the final ribbon product as has been defined above. After application of the coating a template having the desired pattern of shapes (a plurality of ribbons having barbs with spare material between each ribbon form) is placed over the sheet. Next, light is applied to the sheet to remove the protective coating from areas of the sheet where material is to be removed. The resultant sheet etchant protective coating exists only over areas where material is to remain. The sheet is then exposed to a chemical etchant which removes material from the sheet in the unprotected areas. The resultant 76 sheet shown FIG. 6 has numerous perforations where material has been removed the chemical etchant process provides a quick and economical way to form numerous pieces of ribbon stock having accurately formed barbs. The ribbon forms an easily finished sheet by breaking or cutting links 77. The ribbon may be wrapped in to the helical spring implant device as is described above.

The implant devices of the present invention may be delivered to their intended tissue location surgically. FIGS. 8A - 8C show an example of a surgical delivery device that may be used to deliver the implants into tissue such as that of the myocardium of the heart. The delivery device, shown in FIG. 8A, comprises an obturator 80 that includes a main shaft 82, by which it can be gripped and manipulated. The distal end 81 of the shaft 82 is shown in detail in FIG 8B and includes a reduced diameter device support section 84 having a sharp distal tip 86 adapted to pierce tissue. The diameter of the shaft segment 84 is such as to fit closely within the interior of the devices. The proximal end of the segment 84 terminates in a shoulder 88 formed at the junction of a proximally adjacent, slightly enlarged diameter portion 90 of the shaft. The distal end of the device support

Claims

1. A tissue implant device configured to resist migration in tissue comprising a flexible helical spring having at least one coil with at least one barb projecting from the coil that engages surrounding tissue.

2. An implant as defined in claim 1 wherein the at least one barb is proximally facing.

3. The implant as defined in claim 1 wherein the barb projects radially outward from the spring.

4. An implant as defined in claim 1 wherein the barb has a rounded contour.

5. An implant as defined in claim 1 wherein the at least one barb has a sharpened point configured for engaging tissue.

6. An implant as defined in claim 1 wherein the helical spring is formed from a filament having a rectangular cross-sectional profile.

7. An implant device as defined in claim 6 wherein the helical spring comprises a plurality of coils, each having a proximally facing edge along which is formed a plurality of barbs.

8. An implant as defined in claim 1 wherein the spring is formed from a plurality of materials each having different moduli of elasticity.

9. An implant as defined in claim 1 wherein the spring is formed from metal.

10. An implant as defined in claim 9 wherein the metallic material is stainless steel.

11. An implant as defined in claim 1 wherein the moduli of elasticity of the spring varies along its length.

12. An implant as defined in claim 1 wherein the spring is formed from a filament that has been etched from a flat sheet of material and wound into a spring configuration.

13. An implant as defined in claim 12 wherein at least one barb is formed into the filament during the etching process.

14. A method of forming a tissue implant device comprising:

forming a ribbon having at least one projecting barb shape on an edge of the ribbon in a sheet of material by a photochemical etching process;

separating the ribbon formed from the sheet of material; and

wrapping the ribbon form into a helical coil shape, forming the ribbon so that it retains the coil shape.

15. Cancelled

16. A method as defined in claim 15 wherein at least one barb is formed along an edge that will be proximally facing after the ribbon is wrapped into a coil shape.

17. A method as defined in claim 15 wherein a plurality of barb shapes are formed along an edge of the ribbon form so that the resultant coil ribbon has a plurality of projecting barbs along one edge of the coil.

18. A method of forming a tissue implant device as defined in claim 15 further comprising forming a plurality of ribbons in a single sheet of material by photochemical etching process.

19. A method of implanting a tissue implant device comprising:

providing a flexible helical spring having at least one coil with at least one projecting barb that engages surrounding tissue;

providing a delivery device having a penetrating distal tip and being configured to hold the tissue implant for delivery into tissue;

advancing the delivery device and loaded tissue implant into biological tissue so that the tissue is penetrated and the implant is inserted into the tissue;

releasing the tissue implant into the tissue;

withdrawing the implant delivery device.

20. A method of delivering a tissue implant device as defined in claim 19 wherein the tissue is accessed surgically.

21. A method of delivering a tissue implant device as defined in claim 19 wherein the biological tissue is accessed percutaneously.

22. A tissue implant device as defined in claim 9 wherein the spring is formed from a nickel titanium alloy.

23. A tissue implant device as defined in claim 2 wherein the barb projects proximally away from the edge of the spring.

24. A tissue implant device as defined in claim 3 wherein the barb projects radially outward from the edge of the spring at an angle inclined in the proximal direction.

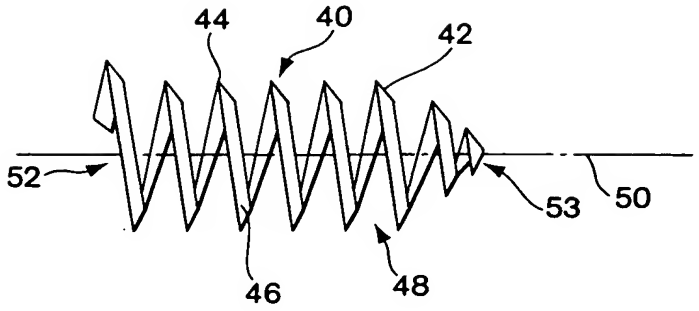

Fig. 1

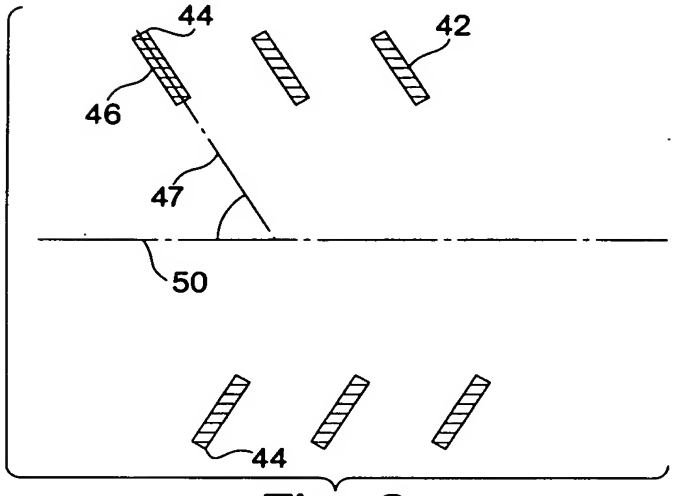

Fig. 2

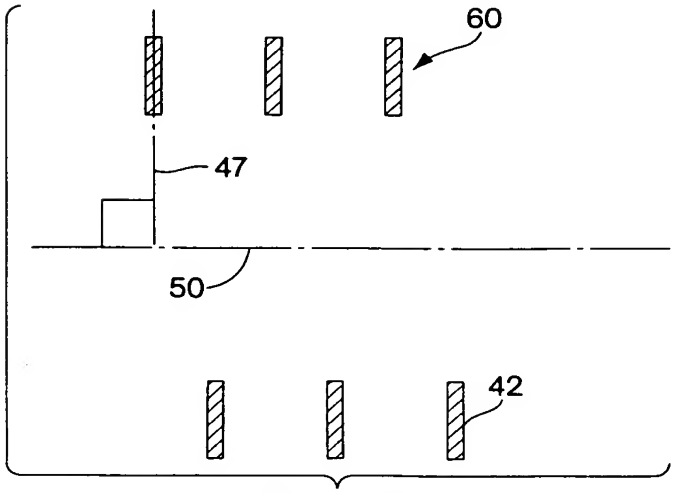

Fig. 3

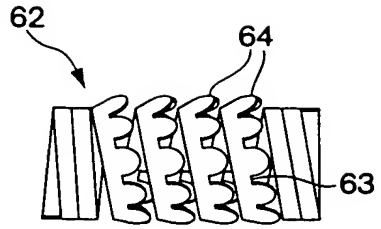

Fig. 4

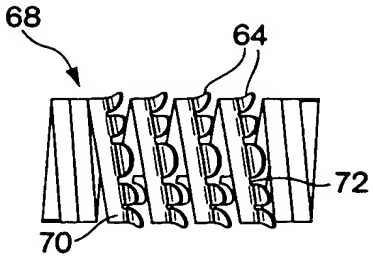

Fig. 5

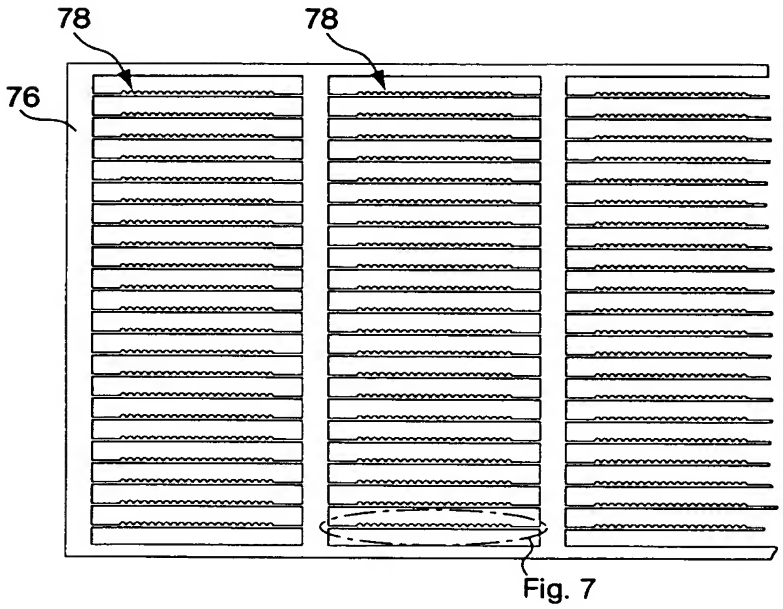

Fig. 6

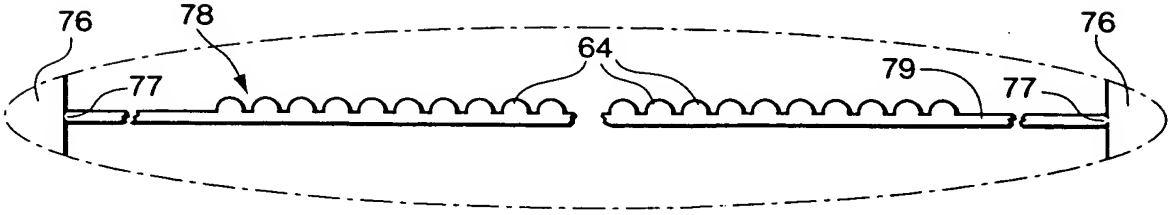

Fig. 7

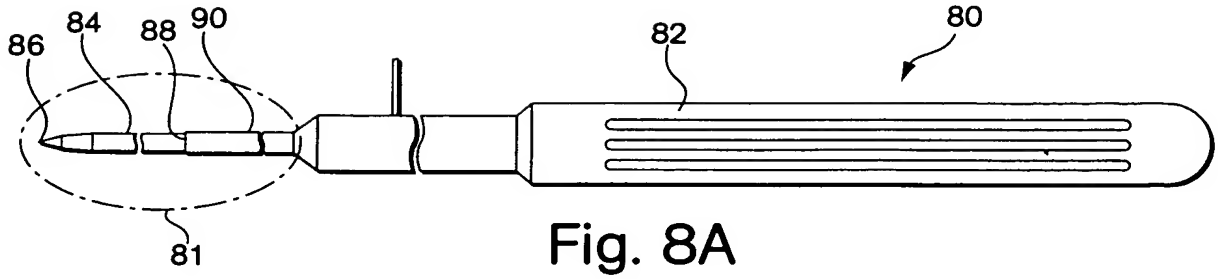

Fig. 8A

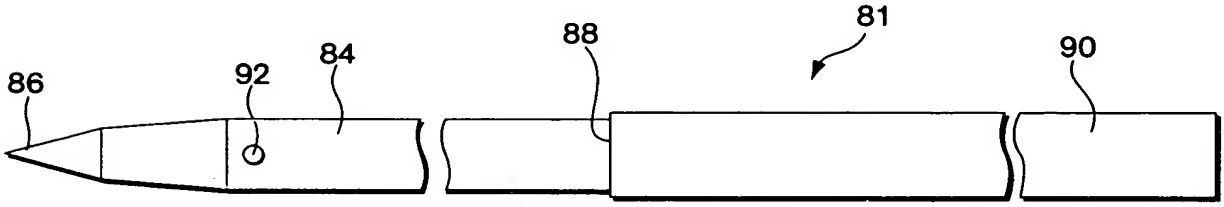

Fig. 8B

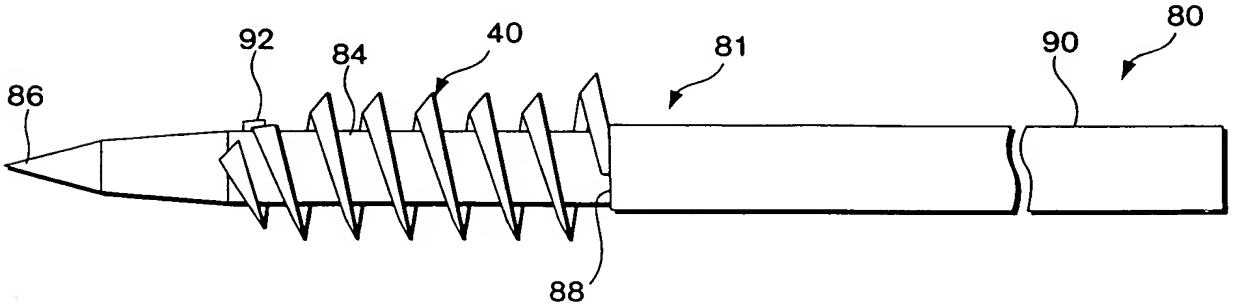

Fig. 8C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/20574

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61F 2/06; A61M 25/00
US CL :623/1.15, 1.22, 1.36, 901

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/1.15, 1.22, 1.36, 901

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST--U.S. PATENTS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	EP 0 876 803 A2 (C.R. BARD, INC) 11 November 1998, col. 2, lines 34-41; col. 2, line 52 - col. 3, line 29.	1-7, 9-10 ---------- 8, 11-13, 15-18
Y	US 5,833,699 A (CHUTER) 10 November 1998, col. 5, lines 39-64; col. 7, lines 39-49.	8, 11-18
Y	US 5,370,683 A (FONTAINE) 06 December 1994, Abstract; col. 3, lines 21-32.	12-13

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 18 OCTOBER 2000	Date of mailing of the international search report 16 NOV 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer CHOON P. KOH Telephone No. (703) 305-1232

Form PCT/ISA/210 (second sheet) (July 1998)★